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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,572	04/04/2005	Emi Sumida	3190-073	1410

33432 7590 01/15/2008

KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
01/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,572	SUMIDA ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2007 and 28 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6 and 8-21* is/are pending in the application.

4a) Of the above claim(s) *12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 5, 6, 8-21 are pending. Claims 1, 2, 5, 6, 8-11 are considered on the merits. Claims 12-21 are withdrawn from consideration as being drawn to a non-elected invention. The elected species is "polyamino acid".

Drawings

The drawings were received on 12/28/07. These drawings are acceptable.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, 6, 8-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,397,479 [IDS] in combination with Maeda *et al.* [U] or US 6,673,629 [A] or Danon [V].

The claims are directed to a method of producing a platelet rich plasma from blood comprising:
adding a water soluble polyamino acid which is a homopolymer to the blood thereby sedimenting the red blood cells in the blood,
separating the sedimented red blood cells and the platelet-rich plasma.

US 5,397,479 disclose a method of separating red cells from blood comprising adding aggregators of red cells such as polysaccharides or proteins to the blood (col. 1, l. 60). Specifically disclosed protein aggregators are fibrinogen, gamma globulin (col. 2, l. 29). Also disclosed is the criticality of the concentration of the aggregator used in the sedimentation method (col. 3, ls. 1-19). The supernatant contains both the platelets and the leukocytes in plasma (col. 4, l. 39).

Maeda *et al.*, disclose that polyglutamic acid is an aggregator of red cells (abstract). Also disclosed is the criticality of the molecular weight of the polyglutamic acid used in the method in that a polyglutamic acid with a mw of 8,000 inhibited aggregation, while a mw of 20,000 accelerated the rate of sedimentation.

US 6,673,629 discloses that polycationic compounds, in particular polyhistidine are aggregators of red blood cells (col. 6, l. 66).

Danon disclose that pLys is an agglutinator of red cells. Also disclosed is the criticality of the molecular weight of pLys and the criticality of the interrelationship of the chemical nature of the polybase and the molecular weight of the polybase (page 289).

The substitution of polyglutamic acid or polyhistidine or polylysine or any polycationic peptide for the aggregator in the method of US 5,397,479 would have been obvious because Maeda *et al.* or Danon or US 6,673,629 disclose that these compounds are aggregators of red cells. This is considered to be the substitution of equivalents known in the art for the same purpose, that is, red cell agglutination/aggregation.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 11/21/07 have been fully considered but they are not persuasive.

Applicants state that the primary reference of Kass *et al.* does not disclose obtaining PRP by accelerating the sedimentation of RBCs. Please see US '479 col. 4, l. 39, where it is stated that the plasma after agglutination of the RBCs contained leukocytes and platelets. The claimed method does not have an subsequent steps after separating the red cells which have been aggregated; therefore, the method steps of the reference would produce the same product as the method steps of the instantly claimed method because the steps are the same. A plasma which has been enriched in platelets as well as leucocytes as disclosed in US '479 is the product of the process as disclosed. In example 7 of the instant application, the only step disclosed is the addition of the polyamino compound to whole blood and allowing the RBCs to settle. The supernatant appears to be called platelet rich plasma. This is the same product as produced in US '479. It is merely that US '479 is more interested in the leucocytes in the supernatant rather than the platelets which are also inherently present. The steps of the method are the same and the product is the same, merely called different names.

Cited as being of interest but not against the claims at this time is Katchalsky *et al.* [U] who disclose that polybases such as polylysine hydrobromide, polyornithine hydrochloride, polyarginine sulfate are agglutinaters of erythrocytes, while polyacids such as polyaspartate sodium, polyglutamate sodium are not.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

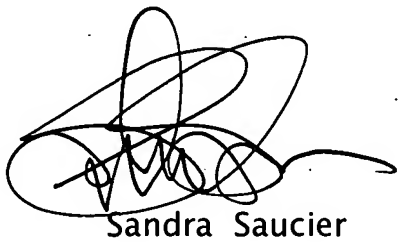
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on

the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651